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APPLICATION NO.	FYLING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
09/108,189	07/01/1998	HOWARD TANNER	23660-00611	9021	
25243	7590 12/01/2001				
COLLIER, SHANNON, SCOTT, PLLC 3050 K STREET, NW SUITE 400			EXAMINER		
			THISSELL, JEREMY		
WASHINGTON, DC 20007			ART UNIT	PAPER NUMBER	
			3763	· · · · · · · · ·	
			DATE MAILED: 12/01/2001	DATE MAILED: 12/01/2001	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/108,189 Applicant(s)

Examiner

Jeremy Thissell

Art Unit 3763

Tanner et al.

	The MAILING DATE of this communication appears	on the cover sheet with the corr				
A SH	or R eply ORTENED STATUTORY PERIOD FOR REPLY IS SET MAILING DATE OF THIS COMMUNICATION.	TO EXPIRE3 MON	TH(S) FROM			
- Exter afr - If the be - If NO co - Failur - Any r	asions of time may be available under the provisions of 37 Coter SIX (6) MONTHS from the mailing date of this communic period for reply specified above is less than thirty (30) days considered timely. period for reply is specified above, the maximum statutory mmunication. The to reply within the set or extended period for reply will, be reply received by the Office later than three months after the reply patent term adjustment. See 37 CFR 1.704(b).	eation. a, a reply within the statutory minim period will apply and will expire SIX y statute, cause the application to b	um of thirty (30) days will (6) MONTHS from the mailing date of this ecome ABANDONED (35 U.S.C. § 133).			
Status						
1) 💢	Responsive to communication(s) filed on Aug 27,	2001	•			
2a) 💢	This action is FINAL. 2b) This action is non-final.					
3) 🗆	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.					
Disposi	tion of Claims					
4) 💢	Claim(s) 82, 85-87, and 96-114	is/a	are pending in the application.			
4	la) Of the above, claim(s)	is/	are withdrawn from consideration.			
5) 💢	Claim(s) <u>104-114</u>		_ is/are allowed.			
6) 💢	Claim(s) 82, 85-87, 96-100, 102, and 103		_ is/are rejected.			
7) 💢	Claim(s) <u>101</u>		_ is/are objected to.			
8) 🗀	Claims	are subject to rest	riction and/or election requirement.			
Applica	tion Papers					
9) 🗌	The specification is objected to by the Examiner.					
10)	The drawing(s) filed on is/are	·				
11)	The proposed drawing correction filed on	is: a)□ approve	d b)□ disapproved.			
12)	The oath or declaration is objected to by the Exam	iner.				
13) ☐ a) ☐	under 35 U.S.C. § 119 Acknowledgement is made of a claim for foreign part of the priority documents have a complete or the priority of the certified copies of the priority of	ve been received. ve been received in Application focuments have been received eau (PCT Rule 17.2(a)).	n No in this National Stage			
14)	Acknowledgement is made of a claim for domestic					
		promy ander de didici 3 11	- 10,·			
Attachm		18) Interview Summary (PTO-413) Pa	N-/-)			
 15) Notice of References Cited (PTO-892) 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 		18) Interview Summary (PTO-413) Paper No(s) 19) Notice of Informal Patent Application (PTO-152)				
_	formation Disclosure Statement(s) (PTO-1449) Paper No(s).	20) Other:				

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by

another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title

before the invention thereof by the applicant for patent.

2. Claims 82, 85-87, 96-98, 100, and 102 are rejected under 35 U.S.C. 102(e) as being

anticipated by Hermann et al (US Pat No. 5,599,305).

Hermann teaches a introducer sheath having a positioning balloon 78 (see figure 6), and a

sealing material 38 (see figure 8) in the sheath for surrounding and sealing the passage around surgical

instruments introduced through the sheath. Hermann distinctly shows in figure 3 and teaches in

col. 10, lines 4-9) that the sealing material does not readily form a passage when it is inserted in the

housing (normal arrangment during use). Figure 4 is merely a drawing of the material if it were not

inside the device. Hermann also teaches inflation lumens 80/82 (running along the instrument

passageway) for the balloon(s). Lastly, Hermann teaches that the inner liner is formed of a polymer

(col. 6, lnes 21-24).

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness

rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such

that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in

which the invention was made.

4. Claim 99 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hermann et al

(US 5,599,305).

Hermann teaches all the claimed subject matter but does not specifically teach that the outer

surface of the device is made of silicon. However, Hermann does teach that the inner surface is

coated with silicone in order to provide lubricity (col. 3, line 67). Since silicone is a well known

lubricious material used to manufacture many different compontents of catheters, and since Hermann

uses silicone to provide lubricity in the inner lumen, one would have found it obvious to choose

silicone for the outer surface in order to provide a lubricious surface to facilitate insertion of the

device.

5. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hermann '305 in

view of Fettel et al (US 3,978,863).

Hermann teaches substantially all the claimed subject matter but does not teach that saline is

used to inflate the balloon. However, the use of saline is universal in the art of catheters, and this

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point is supported by Fettel, who teaches that in "the most commonly used prior art catheter...a fluid,

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such as saline...is used to expand the balloon" (col. 1, lines 46 and 63-65). Saline is typically used

instead of a gas when the device is used intravascularly in case the balloon breaks, because if the

balloon breaks and the gas escapes into the vasculature, the highly compressible gas will allow the

patient's blood pressure to drop too far thus rendering the circulation ineffective causing the death

of the patient. Saline is also used because it is most similar to the fluid throughout the body and

consequently creates little if any imbalance when introduced to the body. In view of this extreme

commonality and the teachings of Fettel, it would have been obvious to use saline as taught by Fettel

to inflate the balloon of Hermann particularly during intravascular procedures in order to prevent the

entry of a gas into the vascular system.

Allowable Subject Matter

6. Claim 101 is objected to as being dependent upon a rejected base claim, but would be

allowable if rewritten in independent form including all of the limitations of the base claim and any

intervening claims.

7. Claims 104-114 are allowable over the prior art of record.

8. The prior art does not teach that the sealing material is a self-sealing gel-like material, but

rather a foam

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Response to Arguments

9. Applicant's arguments filed 27 August 2001 have been fully considered but they are not

persuasive.

Again, the examiner takes the position that Hermann DOES teach that the sealing material

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does not readily form a passageway (i.e. lumen).

Applicant pointed out the passage at col. 7, lines 50-54, which states,

"When the foam insert is disposed within the interior housing of the cavity, however, the

insert is compressed sufficiently to close the lumen. The resilient nature of the foam will permit the

lumen to reopen as the catheter is advanced therethrough."

This passage reinforces the examiner's position that the lumen is "closed" (i.e. no lumen) until

a catheter is advanced through the insert, at which point the resilient nature of the insert allows it to

stretch open.

Conclusion

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy

as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS

from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy Thissell whose telephone number is (703) 305-5261, or to Supervisory Patent Examiner Angela Sykes at (703)308-5181.

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November 7, 2001

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Oungeli D. Ash.